Appln No.: 09/381,556
Amendment Dated: May 23, 2005
Reply to Office Action of May 17, 2004

REMARKS/ARGUMENTS

This is in response to the Office Action mailed May 17 ,2004 for the above-captioned application and is filed with a Request for Continued Examination and a Petition for Extension of time filed in lieu of an Appeal Brief. Reconsideration and further examination are respectfully requested.

Claims 38-40 have been canceled, and claims 4 and 6 have been amended.

The Examiner has rejected claims 1-22 for obviousness type double patenting in view of US Patent No. 6,051,428. As previously indicated, Applicants will file a terminal disclaimer if such is appropriate upon consideration of claims found to be allowable in this case.

Claim 4 has been amended to refer to in vivo therapy, and claim 5 has been amended to refer to ex vivo therapy consistent with the Examiner's suggestion. This is believed to overcome the rejection of claims 4-6 under 35 USC § 112. Applicants thank the Examiner for her clear comments on this point.

The Examiner has withdrawn the rejection of 36 and 37 under 35 USC § 101 as being directed to non-statutory subject matter, but states that the claims "do not encompass or read on any host animal in which the tumor cells may reside." Applicants point out that the claims read on certain tumor cells, and that they read on these cells wherever they may exist, including in a host organism. They do not read on the host organism per se, but a making a transduced organism containing tumor cells within the scope of the invention would still be an act of infringement. If this is inconsistent with the Examiner's understanding, then the basis for some other understanding should be explained.

The Examiner also rejected claims 1-3, 7-37 as anticipated by Boursnell, US Patent No.6,334,445. Applicants argument with respect to the insufficiency of the Boursnell reference relates to the question of whether a reference must comply with the disclosure requirements of all of § 112, first paragraph, that is with both the enablement requirement and the written description requirement, or whether some apparently very minimal level of enablement is sufficient. The examiner's response to this appears to be two-fold. First, she argues that the cases do not establish that a written description of the invention is a requirement for a reference to be anticipatory. Second, she apparently argues that Boursnell would provide a written description of possession of the invention in any event. Applicants respectfully disagree with both arguments.

The case law that relates to the sufficiency of disclosure dates from a time when written description was a new matter rejection applied to a case, and not to written description in its present incarnation. To say that a reference can anticipate something that the inventors had not

even invented, however, and thus not need provide a "written description" as that term is now used presents an absurdity. The whole rationale for anticipation as a reason for refusing a patent is that a new patent should not issue to take something that was already known away from the public. That which has not actually been invented cannot be taken away, and therefore should not be a bar to issuance of a patent.

What then should the standard of disclosure be for the prior art. The examiner states that Boursnell "provides substantial direction for making mixtures of recombinant HSV amplicons and packaged HSV vectors which encode **an** immunomodulatory or therapeutic gene." Office Action, page 6. This, however, is not what is presently claimed. The present claims are directed to vectors that contain 2 genes, and none of the disclosure cited by the Examiner provides any evidence of possession of such an invention by Boursnell. The sole reference to the invention for which Boursnell is being offered as anticipatory is at Col. 7, line 67, Col. 8, line 3 which states that "where nucleotide sequences encoding more than one immunomodulating protein are inserted, they may comprises more than one cytokine or may be a combination of cytokine(s) and accessory molecules." As prevoiusly stated, there are no examples of such structures, and no basis to conclude that Boursnell was in possession of any embodiments or had in fact invented nucleotide sequences encoding two or more immunomodulatory proteins. The reference does not provide any information about the properties of such species, or whether they provide meaningful utility. This off hand remark in Boursnell is therefore no more than speculative science fiction, which should not form the basis for an assertion of anticipation.

Applicants further note that there is no disclosure in Boursnell of specific combinations of genes as set forth in the present claims. For example, claims 19, 35, and 653 all recite a combination of interleukin-2 and interleukin 12, while claims 21, 33 and 55 recite the specific combination of RANTES and B7.1. Rejections of these claims as anticipated is inappropriate.

Applicants further note that claims 16 and 50 require use of a mixture of different species of amplicons (that is amplicons containing different genes), that claims 23-35 claim such a mixture of amplicons, and that claim 37 claims tumor cells transduced with such a mixture. The examiner has not identified where in the Boursnell application the invention of these claims is disclosed. The most Boursnell discloses is amplicons with two genes, not a mixture of amplicons with different genes. Thus, there can be no basis for an anticipation rejection of these claims.

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For the foregoing reasons, Applicants submit that the present claims are in form for allowance, subject to the filing of an appropriate terminal disclaimer. Favorable reconsideration is respectfully urged.

Respectfully submitted,

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